

6360 I-55 North, Suite 400 Jackson, MS 39211 licensing@mbp.ms.gov Office: 601-899-8880 Fax: 601-899-8851 www.mbp.state.ms.us



# DRUG FACILITY PERMIT APPLICATION CHECKLIST

Check if Complete	ITEM	Office Use Only
	Completed Application (ALL required fields, attachments and fees must be included for the application to be considered complete)	
	Completed Fingerprint Card, Background Questionnaire, Verification Form and Signed and Notarized Affidavit for the Designated Representative and EACH Owner	
	Copy of your current home state license/permit	
	> Most recent inspection report	
	> Copy of DEA registration (if applicable)	
	> Documentation of current FDA registration	
	> Evidence of Surety Bond	
	Third Party Logistics Providers and Virtual Entities must provide a list of all trading partners they provide service for	
	> Appropriate Signatures must be affixed	
	<ul> <li>PAYMENT OF FEES: (Fees are NON-REFUNDABLE)</li> <li>\$500 Application Fee</li> <li>\$50 Controlled Substances Permit Fee (If Applicable)</li> <li>\$40 Background Check Fee for Designated Representative and EACH Owner</li> </ul>	
	<ul> <li>Example: 1 DR and 4 Owners would total \$200 for Background Checks</li> <li>Make checks payable to MISSISSIPPI BOARD OF PHARMACY</li> </ul>	
	<ul> <li>Check may be submitted cumulatively (one check) or in multiple checks</li> </ul>	
	> THE ENTIRE APPLICATION (ALL PAGES INCLUDING FINGERPRINT DOCUMENTS) MUST BE MAILED TO: MISSISSIPPI BOARD OF PHARMACY	
	Attention: Licensing Division 6360 I-55 North, Suite 400 Jackson, Mississippi 39211	

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### DEFINITIONS OF THE TYPES OF DRUG FACILITY PERMITS

#### WHOLESALE DRUG DISTRIBUTOR (WDD)

A company engaged in the distribution of their own product. They own, house and ship their product in their name or a product licensed to them by another company. A Wholesale Drug Distributor has product manufactured under a contract or trade agreement with a manufacture or purchases product from another company to house and ship. They must be registered with the FDA. State license required in home state and all states they ship product to. If they ship control substance product, must have a DEA registration. MUST FOLLOW DSCSA REGULATIONS.

#### **MANUFACTURER**

Manufactures product for themselves or other companies under contract or trade agreement. Must be registered with the FDA. Must be registered with the DEA if they produce control substance product. License in home state required. MUST FOLLOW DSCSA REGULATIONS.

#### THIRD PARTY LOGISTICS (3PL)

This facility ships pharmaceutical product for other companies. Must have contract or trade agreement with each company they ship for. This facility does not take ownership of product, but does store product, control product inventory and shipping/receiving records for other pharmaceutical companies. MUST FOLLOW DSCSA REGULATIONS.

#### **RE-PACKAGER**

This facility packages product for other companies under a contract or trade agreement and does not take ownership of the product. Must be registered with the FDA. MUST FOLLOW DSCSA REGULATIONS.

#### **VIRTUAL**

A facility that is registered with the FDA, owns or licenses a product, but never receives the product into their facility. They contract to have product made by an FDA registered pharmaceutical company. They also contract to have it shipped by an FDA registered third party logistics company. They must be licensed in all states they have product shipped to and their home state. They are required to maintain an office with full-time employee(s), and keep records on their products, have SOPs and handle their product complaints and adverse events. MUST FOLLOW DSCSA REGULATIONS.

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## DRUG FACILITY PERMIT

Check **ONLY ONE** per application – (USE SEPARATE APPLICATION PER PERMIT TYPE):

-Manu	facturer	
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- □ -Virtual
- -Re-packager
- ☐ -Wholesale Drug Distributor (WDD)
- ☐ -Third Party Logistics Provider (3PL)
- -Veterinary Drug Distributor
- -Reverse Distributor

# Application for Permit and Changes In Existing Permits.

(Changes require a new application and fee.)

#### Purpose of Application:

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- ☐ -Change of Location
- -Change of Facility Name
- ☐ -Change in Designated Representative
- ☐-Change of Ownership



### **Entity Name:**

Permit Period:
January 1, 2017
through
December 31, 2017
\$500.00 ANNUALLY

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#### **DRUG FACILITY PERMIT**

~ Instructions ~

#### **READ CAREFULLY**

The following Application for Drug Permit should be used for ALL Drug Permit entities, including MANUFACTURER, VIRTUAL, RE-PACKAGER, WHOLESALE DRUG DISTRIBUTOR (WDD), THIRD PARTY LOGISTICS PROVIDER (3PL), VETERINARY DRUG DISTRIBUTOR and REVERSE DISTRIBUTOR. A separate application and fee must be provided for each permit type.

#### **BE PROMPT AND ON TIME**

A LATE FEE OF \$250.00 WILL BE ASSESSED ON ANY APPLICATION RECEIVED AFTER DECEMBER 31<sup>ST</sup>. THE APPLICATION WILL NOT BE PROCESSED UNTIL THE LATE FEE IS RECEIVED. FAILURE TO APPLY IN A TIMELY MANNER MAY RESULT IN DISCIPLINARY ACTION BY THE BOARD AND ADDITIONAL MONETARY PENALTIES.

#### DO NOT FORGET TO INCLUDE PAYMENT

ALL FEES ARE NON-REFUNDABLE and must accompany this application for the application to be considered complete. [Make all checks payable to the MISSISSIPPI BOARD OF PHARMACY.]

THIS APPLICATION, BACKGROUND CHECK DOCUMENTS AND REGULATIONS CAN BE DOWNLOADED FROM OUR WEBSITE: www.mbp.state.ms.us

#### **ALL DOCUMENTS SHOULD BE MAILED TO:**

#### MISSISSIPPI BOARD OF PHARMACY

Attention: Licensing Division 6360 I-55 North, Suite 400 Jackson, Mississippi 39211

For questions please email:

licensing@mbp.ms.gov

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#### Permit Period is January 1st through December 31st Annually.

Fee \$500.00

- Any answers, explanations, or omissions found to be false or deceptive may result in the Board denying issuance of, or permanent revocation of, your permit in the State of Mississippi.
- Type or print answers to all questions. If more space is required, attach supplemental page(s) identifying each item corresponding to the application.

Section 1: LOCATION OF F	ACILITY REQUESTING	PERMIT	
□ Within Mississippi □	Outside of Mississippi	(Current Permit #	if applicable)
Section 2: APPLICANT (BU	SINESS ENTITY) INFORM	IATION	
Name of Business:	Federal Tax ID# (REQUIRED) FDA #		
Circle One:	(REQUIRED)		
Sole Prop / Inc / LLC / Other:	Please list ALL Trade Names used. Use a senar	all numbers that apply to the facility.	
DBA/1 rade Name(s) (11 applicable):	rease list <u>rease</u> trade raines used. Ose a separe	ne, attached page if necessary.)	
Name of Entity's Parent Company: (	f the corporate structure extends past a parent, att	ach complete details of the corporate structure.):	
Entity Physical Address: (Including City, Sta	Entity Phone #:	Fax	#:
Mailing Address (If different): (Including	g City, State & Zip)		
State in which the Entity is incorpora	ited:   We	bsite URL(if applicable):	
Corporate Offices Direct Telephone #	<b>#:</b>		
Does the Entity hold any other license (If yes list details – List all on separate sheet if needed.)	es, registrations or permits in	Mississippi?	
Section 3: DESIGNATED RI (This cannot be a ca		ACT INFORMATION (REQ	UIRED)
Name:		Social Security #:	
Direct Phone #:	Cell Phone #:	Fax #:	
E-mail Address:			
*AN INDIVIDUA	L CAN BE A "DESIGNA IN ONLY ONE FAC	ATED REPRESENTATIV	E"

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Section 4: ENTITY OWNERSHIP INFORMATION  (REQUIRED) [If corporately owned, provide details of corporate structure.]				
Name	Title	Address		
Section 5: FACILITY/APPLI	CANT BACKGROUN	ND INFORMATION		
Has the Drug registration of state or federal law ever be explanation and certified of the state of the	een suspended or revok	/applicant under any local, ted? (If yes, attach an and records.)	□ □ YES NO	
2) Has the Applicant ever be proceeding involving alleg (Attach specific details sep	gations of fraud, illegal		□ □ YES NO	
Has the Applicant had a bi illegal or dishonest activiti	usiness relationship tern es? (Attach specific de	minated for any fraudulent, tails separately.)	□ □ YES NO	
Third Party Logistics Prove trading partners they provi		ies must provide a list of all	ATTACH	

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5) Has the Applicant, parent company or any company or organization controlling operations experienced any data security breaches or HIPAA security breaches? (If YES please attach all pertinent information concerning any data security breach. Any future data security breach must be reported immediately to the Mississippi Board of Pharmacy.)	VES NO
6) Has the Applicant ever been denied issuance of, or pursuant to disciplinary proceedings, refused renewal of a license, registration or permit by any Board or agency in Mississippi or any other state? (If yes, please attach an explanation and certified copies of all documents and records.)	□ □ YES NO
7) Have any of the owners, partners of the firm, or officers of the corporation ever been convicted of any crime under the laws of the United States, Mississippi or any other State pertaining to the manufacturing, distribution, sale or dispensing of drugs or narcotics? (If yes, please attach an explanation and certified copies of all documents and records.)	
What education, training, experience, or combination of these are required of employees to assure assigned functions are performed in a manner that ensures prescriptions drug quality, safety, and security will be maintained at all times as required by law and regulation? (Attach narrative or SOP with details.)	ATTACH
Section 6: OTHER REQUIRED DOCUMENTATION	
1) Provide the most recent inspection reports for physical facility.	ATTACH
<ol> <li>Provide a list of all states in which licenses/permits/registrations are held. (Include numbers, expiration dates, status, etc.)</li> </ol>	ATTACH
<ol> <li>Provide a copy or documentation of your most current FDA registration. (This applies to all Virtual, Re-packager, WDD and 3PLs.)</li> </ol>	ATTACH
Section 7: SURETY BOND	
TITLE 30: PROFESSIONS AND OCCUPATIONS Part 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS  2. B. Provide evidence of a surety bond made payable to the MISSISSIPPI BOARD OF PHARMACY in the amount of \$100,000. (\$10,000 for an entity whose annual gross receipts total \$10,000 or less for the previous tax year.)  (Attach evidence of Surety Bond.)	АТТАСН
Section 8: REQUIRED BACKGROUND CHECK	
TITLE 30: PROFESSIONS AND OCCUPATIONS Part 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS  2. C. Submit background checks for owners and Designated Representative, including fingerprinting. (Attach completed Fingerprint Card, Background Check Affidavit Questionnaire / Fingerprint Verification and return with application along with a Background Check fee of \$40.00 for DESIGNATED REPRESENTATIVE AND EACH OWNER.)	COMPLETE AND ATTACH FORM AND FINGERPRINT CARD FOR EACH INDIVIDUAL.

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#### (COMPLETE IF APPLICABLE / ATTACH PROOF OF DEA REGISTRATION)

### APPLICATION FOR REGISTRATION TO HANDLE CONTROLLED SUBSTANCES

January 1, 2017 – December 31, 2017 FEE - \$50.00

Name of Business:	Federal T	ax ID#:	DEA #:	
Street Address:				
City:	State:	Zip:	County:	
Applicant's Signature:				
Print or Type Name:				
REGISTRATION NUMBER:		JSE ONLY	FILE NUMBER:	
DATE ISSUES:			RECEII I NOMBER.	

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This form must be completed, notarized and accompany each application signed by the Designated Representative (DR).

#### AFFIDAVIT OF APPLICANT

WHOEVER KNOWINGLY AND WILLFULLY MAKES OR CAUSES TO BE MADE A FALSE STATEMENT OR REPRESENTATION MAY BE PROSECUTED UNDER APPLICABLE STATE LAWS. IN ADDITION, KNOWINGLY AND WILLFULLY FAILING TO FULLY AND ACCURATELY DISCLOSE THE INFORMATION REQUESTED MAY RESULT IN DENIAL OR REVOCATION OF PERMIT.

I, the above-named applicant, state, under oath, that I am the person referred to in this questionnaire and that all the statements herein contained are each and all strictly true in every respect. I understand that false or forged statements made in connection with this questionnaire constitutes grounds for the Mississippi Board of Pharmacy to refuse to issue or renew, suspend, restrict, revoke or take other disciplinary action against my permit in the State of Mississippi. I understand that if I am issued a permit, failure to comply with the laws or regulations governing the distribution of drugs in this state, or any other state, will be cause for disciplinary action by the Mississippi Board of Pharmacy. Further, that I give my consent for the release to the Mississippi Board of Pharmacy of any and all records or any other information which may relate to the above questions or my practice from any source or jurisdiction.

Signature of Designated Representative	Printed Name		Date
Sworn to before me and subscribed in m	ny presence this	day of	, 20
(seal)		Notary Public My Commission I	Expires

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